Chiesi

CLINICAL RESULTS SUMMARY

A study to compare the safety of CHF5993 inhalers when given with two different propellants in people with asthma

Thank you!

Chiesi, the sponsor of this study, thinks it is important to share the results of this clinical study with the community and would like to thank the participants who were part of this study, the site staff, caregivers, and everyone else who made this study possible.

A clinical study participant belongs to a large community of participants around the world who help researchers answer important health questions and discover safe and effective medicines.

Please note: This summary only shows the results of a single study. Other studies on the same drug may have different findings. The results of many studies are needed to understand how a medicine works. No healthcare decisions should be made based on the results of a single study.

About this summary

This document is a short summary of this study's main results, written for study participants and the public. More information about this study can be found at the links provided at the end of this document.

About this study

Why was this study needed?

Asthma is a long-term condition that affects the airways in the lungs, leading to occasional breathing difficulties. It is a condition with symptoms such as wheezing attacks, coughing, shortness of breath, and difficulty in breathing. Currently, patients with asthma are often treated with inhaled therapies. In some cases, these are medicines that you breathe in through a spray using pressurised metered dose inhalers (pMDI). The pMDI is a device that delivers a specific amount of inhaled medicine with each puff. These devices use a gas, known as a propellant, to create a puff of medicine which is inhaled by the patient. The pMDIs currently use a propellant that can contribute to global warming, so an alternative propellant is being tested. For this study, researchers wanted to assess the safety of the study drug with a new environment-friendly propellant (HFA-152a) in comparison with the marketed propellant (HFA-134a).

About the study drug

The study drug is CHF5993, an inhaled drug approved for managing asthma and chronic obstructive pulmonary disease (COPD) in adults.

CHF5993 is a combination of 3 medicines, beclomethasone dipropionate-BDP, formoterol fumarate-FF and glycopyrronium bromide-GB. BDP reduces the inflammation of lungs. FF and GB open up the airways and make breathing easier, although GB works in a different way than FF.

In this study, participants received one of the following treatments:

- Reference treatment: CHF5993 pMDI with propellant HFA-134a.
- Test treatment: CHF5993 pMDI with propellant HFA-152a.

Each puff of either inhaler contained 200 micrograms (µg) of BDP, 6 µg of FF, and 12.5 µg of GB. In this study, participants took 2 consecutive puffs from the inhaler twice every day. So, the total dose in 4 puffs was 800 µg of BDP, 24 µg of FF, and 50 µg of GB, regardless of the propellant.

What was the main goal of this study?

In this study, researchers wanted to answer the following main question:

How well could participants breathe after inhaling CHF5993 with propellant HFA-152a compared with propellant HFA-134a?

To answer this question, the researchers performed lung function tests (otherwise known as spirometry), repeated at different times (before and after inhalations) on the first day of treatment.

These tests helped researchers assess if there were any signs of narrowing of the airways immediately after participants took the study drugs. This way researchers could compare the risk of narrowing of airways between the two propellants.

Throughout the study, researchers monitored the health of participants for any medical problems.

More detailed information about other questions answered in this study is available on the websites listed at the end of this summary.

When and where was this study done?

This study started in **December 2023 and ended in February 2025.**

Participants were from 14 countries.

Country	Number of Participants
Bulgaria	140
Czech Republic	28
Georgia	7
Germany	87
Greece	4
Hungary	27
Italy	4
Netherlands	2
Poland	142
Romania	30
Serbia	39
Slovakia	18
Spain	5
UK	20

An individual study participant could have been in the study for up to 4 months.

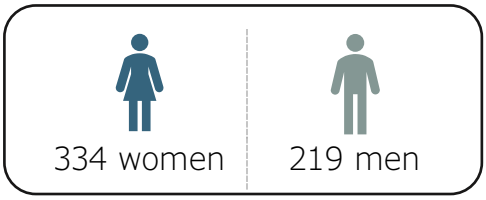
Who could take part in this study?

Participants could be included in this study if they:

- were men or women aged 18 years to 75 years,
- had a body mass index (a measure of body weight in relation to height) between 18 and 35 kilograms for each square meter of body's area,
- were non-smokers or ex-smokers (with limited cigarette use),
- were diagnosed with moderate to severe asthma for at least 6 months before the study started and before they were 50 years old, and
- were on a stable dose of asthma medicines similar to the study drugs for at least 1 month before the study started.

Who was in this study?

This study included 553 participants with asthma between the ages of 18 and 75 years.



What happened during this study?

This was a Phase 3 study comparing 2 inhalers containing the same study drug but different propellants.

In Phase 3 studies, the study drug is given to a large number of participants with the disease condition to learn more about the effects of the study drug and its safety. In particular, this study was done to compare the safety of 2 propellants with same study drug.

Researchers assigned participants to 2 groups in a random way using a computer program. This process is called randomization. It means that each participant could be assigned to any group.

This study was "double-blind". This means that neither participants nor the study doctors knew who was given which inhaler. Studies are sometimes done this way to make sure that trial results are not influenced by this information.

Researchers assigned 553 participants to 1 of the 2 groups in a random way to either receive CHF5993 with propellant HFA-152a or CHF5993 with propellant HFA-134a. The participants were assigned in a way that they have twice the chance to receive CHF5993 with propellant HFA-152a.

The study had up to 7 visits. 2 visits before treatment (Visit 0: pre-screening and Visit 1: screening). 4 treatment visits: Visit 2 on the first day of treatment (Day 1), then Visit 3 after one week, Visit 4 after one month, and Visit 5 after 3 months for health check-ups. Then, 1 final visit or a phone call at follow-up.

This study was done in 4 periods:

Pre-screening (1 Week):

Researchers explained the study to participants, including the restrictions to be respected.

Screening (Run-in) (2 weeks):

During screening visit, researchers checked participants to confirm if they could take part in the study.

Eligible participants were trained on how to use the inhaler and received treatment for the run-in period. A run-in period in a study is a phase before the main part of the study. During this period, all participants receive the same treatment. Participants took CHF5993 with propellant HFA-134a as 2 consecutive puffs from the inhaler twice every day, for 2 weeks. In the run-in period researchers wanted to maintain the participants in similar conditions before starting treatments that would be compared. During this time, the participants had various tests that included lung function test, blood draws, urine tests and other assessments like blood pressure and heart activity (ECG).

Treatment (12 weeks):

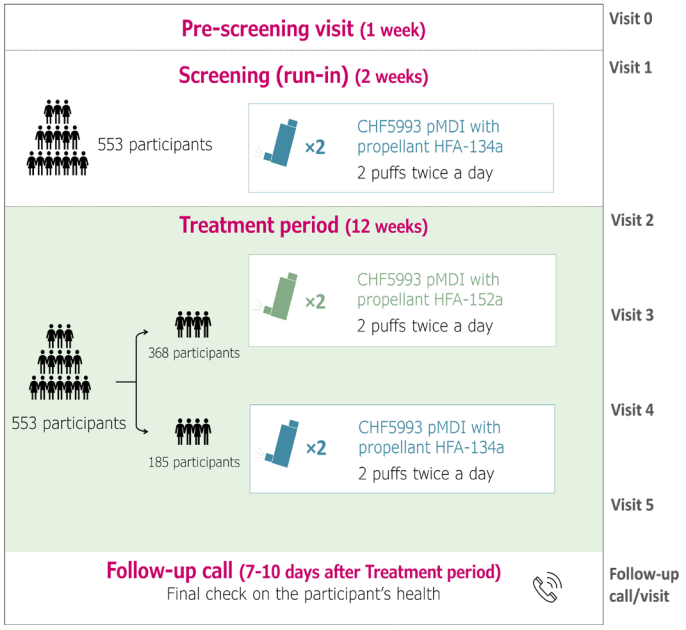
Out of 553 participants, 368 were assigned to receive CHF5993 with propellant HFA-152a, and 185 were assigned to receive CHF5993 with propellant HFA-134a.

Participants who received CHF5993 with HFA-152a or HFA-134a propellant took 2 puffs in the morning and 2 puffs in the evening every day for 12 weeks.

The researchers collected data related to participants' lung function, breathing, and other exams required for the monitoring of participants' health at different times.

Follow-up (7 to 10 days after treatment):

Researchers did a follow-up check on the participants' health status either by phone call or in-person visit.



What was the main result of this study?

How well could participants breathe after inhaling CHF5993 with propellant HFA-152a compared with propellant HFA-134a?

Researchers found that there was no difference in the breathing of participants after inhaling CHF5993 with propellant HFA-152a compared with propellant HFA-134a, at all different times measured on the first day of treatment.

Treatment with both propellants was safe and well-tolerated.

Were there any side effects?

Side effects are unwanted medical problems that happened during the study, which the study doctor believes may be related to the study drug. Only side effects from this study are presented below. Researchers need to consider the results of many studies to understand if any medical problems may be related to the study drug.

Serious side effects

Serious side effects are those that are capable of causing death or cause death, cause disability that lasts for a long time, or require the participant to be in the hospital.

No participants who took the CHF5993 inhaler with either HFA-152a or HFA-134a as the propellant reported serious side effects.

Non-serious side effects

The most common non-serious side effects reported by at least 2 of the participants in any group are presented below.

Most common non-serious side effects reported by at least 2 participants

	CHF5993 inhaler with the propellant	
	HFA-152a (368 participants)	HFA-134a (185 participants)
Yeast infection of the mouth and throat	2	2
Cough	2	1
Dry mouth	2	0
Fungal infection on the tongue	2	0

Participants who stopped the study drug because of side effects

2 participants receiving CHF5993 with HFA-152a propellant stopped the study drug due to side effects of headache and cough.

How was this study useful?

The study was completed as planned.

Results from this study helped researchers understand how well participants could breathe with the CHF5993 inhaler with HFA-152a propellant compared with the CHF5993 inhaler with HFA-134a propellant.

There was a similar effect on airways between treatments, with a low chance for narrowing the airways. Both treatments were safe and well-tolerated by the study participants.

Side effects were comparable between treatments considering the number of participants in each group (percentages similar between both groups).

This means that the study drug with the new propellant (HFA-152a) is as safe as the study drug with the marketed propellant (HFA-134a).

Findings from this study may be used to seek approval for using CHF5993 inhaler with HFA-152a propellant for patients with asthma.

Additional clinical studies with CHF5993 inhaler with HFA-152a propellant are ongoing.

Study information

Full study title: A 12-week double-blind, multicentre, randomised, active-controlled, 2-arm, parallel-group clinical trial to evaluate the safety of CHF5993 pMDI 200/6/12.5 µg HFA-152a, compared to CHF5993 pMDI 200/6/12.5 µg HFA-134a, in subjects with asthma.

Protocol number: CLI-05993AB6-03

EUCT number: 2023-503333-22-00

National Clinical Trial number: NCT06264674

Sponsor: Chiesi Farmaceutici S.p.A

Sponsor's contact information:

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Date of summary: 03-FEB-2026

Where can I find more information about this study?

More information about this study can also be found on the following websites:

- www.clinicaltrials.gov. Use the NCT identifier NCT06264674 in the search field.
- euclinicaltrials.eu/search-for-clinical-trials. Use the EUCT identifier 2023-503333-22-00 in the search field.

If there are any questions about the results of this study, please speak to your doctor. Study participants, please speak to the doctor or staff at the study site.

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Thank You

The sponsor would like to thank the study participants, site staff, caregivers, and everyone else who made this study possible.